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Washington, D.C., March 21, 2017—The National Organization for Rare Disorders (NORD) and Friends of Cancer Research, two leading organizations that collectively represent millions of Americans with cancer and rare diseases, issued the following statement in advance of this week's congressional hearings on the reauthorization of FDA user fees:

"We wish to congratulate the Senate Committee on Health, Education, Labor, and Pensions (HELP) and the House Committee on Energy and Commerce (E&C) for moving forward with the reauthorization of the FDA user fees. This week's hearings represent important steps forward in the renewal of these critical programs.

We also wish to convey our support for the Commitment letters already negotiated and finalized by FDA and regulated industries. The PDUFA Commitment Goals Letter includes several important improvements and advancements to FDA processes and initiatives. These include the continuance of the Patient-Focused Drug Development program, the strengthening of the Breakthrough expedited review pathway, and the expansion of the Rare Diseases program, among others.

The MDUFA Commitment Goals letter also contains several crucial reforms including the further inclusion of patient preference information and patient-reported outcomes in device development and review, as well as the creation of the National Evaluation System for health Technology (NEST).

Our request of the Committees of Jurisdiction and Congress as a whole is simple: please keep the user fee reauthorization process non-partisan, uncontentious, and focused on the patients FDA serves every day.

The FDA largely relies on user fees authorized by Congress to operate. Without the user fees, a majority of drug, biologic, and device reviewers would be laid off, and the necessary review of innovative therapies would be substantially impaired if not halted all together.

The user fee acts are far too important to jeopardize with controversial partisan policy topics. We recognize the desire for additional reforms related to therapeutic development incentives, review, and access. But we respectfully request that attempts to reform these areas without full bi-partisan support are not pursued as part of the UFA reauthorizations.

The cancer and rare disease patient communities rely on FDA to ensure that innovative, safe, and effective treatments reach those in need. We thank the HELP and E&C Committees for moving forward with these critical funding mechanisms, and look forward to their swift and unimpeded passage."